K133263

proteus DIGITAL HEALTH

FEB – 7 2014

510(k) Summary

Submitted by:	Proteus Digital Health Inc.
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Date Submitted:	October 21, 2013

Name of Device

Trade name:	Proteus® Patch Including Ingestible Sensor
Common name:	Ingestible Event Marker
Classification name:	Ingestible Event Marker (21 CFR 880.6305, Product Code OZW, DXH)

Unmodified Device

- Proteus® Patch Including Ingestible Sensor (K131009)

General Device Description

The Proteus Patch is a body-worn sensor that collects physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped user-logged events generated by swallowing the Proteus Ingestible Sensor. The Ingestible Sensor is embedded inside an inactive tablet (the Pill) for ease of handling and swallowing. Once the Ingestible Sensor reaches the stomach, it activates and communicates its presence and unique identifier to the Patch. The Patch stores and wirelessly sends the physiological, behavioral, event, and ingestion data to a general computing device for display.

Intended Use

The Proteus® Patch is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable.

Physical Characteristics

Parameter	Values	
The Patch		
	One-Piece Form Factor: (Cleared under K131524)	**Two-Piece Form Factor: (Modified device)**
Shape	One-piece: ovoid	Two-piece: Rectangular
Size	102mm x 56mm x 10mm	98mm x 42mm x 11mm
Weight	11g	16 g
Battery type	Lithium Manganese (LiMn) Coin Cell	Lithium Manganese (LiMn) Coin Cell
Moisture susceptibility	Water-resistant	Water-resistant
Memory	4 MB	16 MB
Storage temperature	Room Temperature	Room Temperature
Relative humidity	Ambient	Ambient
The Pill		
Shape	Round	
Size	6.5mm x 2.0mm	
Weight	80mg	
Shape	Round	

Technological Characteristics

Parameter	Sensor Technology	Method
Heart rate	Biopotential low-frequency amplifier	Digitized R wave
Activity	Accelerometer	Digitized accelerometer output
Body angle	Accelerometer	Double integration of accelerometer output
Manual event logging	Patient activated button	Digital pulse
Inter-electrode impedance	Biopotential high-frequency amplifier	Digitized impedance from small auxiliary current
Ingestible Event Marker	Bio-galvanically powered ingestible circuit	Volume conduction communication

Summary of Non-Clinical Performance Data

The three-axis accelerometer provided motion and angle relative to gravity data and was validated against a known acceleration applied against each of its three axes.

The biopotential low-frequency amplifier was used to quantify heart rate by measuring R-wave frequency based upon a modified Hamilton-Tompkins algorithm, tested using guidelines set forth in the ANSI/AAMI EC 13 standard.

The Ingestion Sensor was tested for activation time and lifetime after activation.

Summary of Clinical Performance Data

No additional clinical data were required to confirm substantial equivalence to predicate device.

Conclusion

Based on technological characteristics, risk evaluation, and design verification of the Proteus

Patch Including Ingestible Sensor, Proteus Digital Health, Inc. believes that the product is safe and effective, and is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Proteus Digital Health, Inc.
Jafar Shenasa
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065 US

Re: K133263
Trade/Device Name: Proteus Patch, Proteus Ingestible Sensor (accessory)
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW, DXH
Dated: January, 08, 2013
Received: January, 09, 2013

Dear Jafar Shenasa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K133263

Device Name Proteus® Patch including Ingestible Sensor

Indications for Use The Proteus® Patch is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable.

Prescription Use __X__ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.07 09:27:41 -05'00'